



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,630	09/21/2001	Peter Knox	PA 9847	5704

36335 7590 07/25/2006

GE HEALTHCARE, INC.
IP DEPARTMENT
101 CARNEGIE CENTER
PRINCETON, NJ 08540-6231

EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
----------	--------------

1641

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/869,630

Applicant(s)

KNOX ET AL.

Examiner

Ann Y. Lam

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rose et al., 6,015,565, in view of Pines et al., 6,426,058.

Rose et al. disclose the invention substantially as claimed.

More specifically, as to claims 1 and 10, Rose et al. disclose an in vitro method which is a test involving a reaction of one or more biological molecules (col. 49, lines 19-21) and which comprises:

conducting said reaction (col. 49, lines 1-25); and

observing a magnetic response resonance spectrum and/or NMR image of the label during the course of said reaction in order to detect a conformational change in the labeled biological molecule (col. 49, lines 32-35), wherein one of said one or more biological molecules comprises an assay reagent (i.e., the pharmaceutical candidate or alternatively the Glycoprotein B, see col. 49, lines 19-21);

Although Rose et al. teach use of NMR in general to detect a conformational change due to the binding of the candidate to the Glycoprotein B, Rose et al. however

Art Unit: 1641

does not explicitly disclose labeling the biological molecule with hyperpolarized ^{129}Xe to enhance NMR detection. Pines et al. however disclose this limitation.

Pines et al. teach use of NMR spectroscopy for determining structure and conformation of molecules (col. 1, lines 18-22) to analyze, characterize or image a biological sample (col. 12, lines 6-13; and col. 18, lines 61-64.) Pines et al. teach a method of measuring a signal transferred from a hyperpolarized noble gas atom to a non-noble gas NMR active nucleus such as ^{13}C or ^{15}N (col. 15, lines 26-39). Pines et al. teach that the detection is used to study regions of a structure that bind to or otherwise interact with the hyperpolarized noble gas. Such detection is used to study a macromolecule such as a protein (col. 15, line 62 – col. 16, line 6). Pines et al. teach further teaches that hyperpolarization of an NMR active nucleus enhances the noble gas magnetic resonance signal (column 1, lines 12-14; col. 18, lines 31-32.) Furthermore Pines et al. teach that a preferred hyperpolarized noble gas is ^{129}Xe (col. 7, lines 53-54 and col. 9, lines 6-10.) Pines et al. teaches that hyperpolarized xenon can be used to elucidate structures of biologically relevant molecules, such as proteins, by selective polarization transfer to the protons of the specific sites where the xenon binds (col. 30, lines 38-41.)

It would have been obvious to one of ordinary skill in the art to utilize hyperpolarized ^{129}Xe as taught by Pines et al. in the Rose et al. NMR detection of a binding or conformation change because Pines et al. teach that using hyperpolarized ^{129}Xe will enhance the magnetic resonance signal, as would be desirable for obtaining more accurate results.

As to the following claims, Rose et al. teach the limitations as follows.

As to claims 3 and 4, the assay is a binding assay (col. 49, lines 32-35.)

As to claim 5, the molecule is a protein (col. 49, lines 32-33.)

And as to claims 6-9, Rose et al. also does not disclose that the hyperpolarized ^{129}Xe is enriched at a level of 40% or more, or that the degree of hyperpolarisation is 8% or more, or that the method is performed in a solution wherein the solvent has a viscosity in the range of 700 to 1500 mPs, or that the pressure of the xenon gas is at least 5 bar.

Since these claimed ranges are optimum or workable ranges, it would have been obvious to modify the Rose et al. reference to provide these ranges because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum of workable ranges involves only routine skill in the art (In re Aller, 105 USPQ 233.)

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are not persuasive.

Applicant states on pages 2 to 3 that Rose disclose methods for carrying out the detection step, e.g., that binding of the candidate to the glycoprotein B may be observed as a conformation change, which may be detected using nuclear magnetic resonance (NMR). Applicant argues on page 3 that Rose does not disclose that the NMR spectrum and/or image is observed during the course of the reaction as required by the present

claims. This is not persuasive because the detection of the binding is a detection during the course of the reaction.

Applicant also states that Pines teaches the use of ^{129}Xe to enhance NMR detection but there is nothing in Pines to suggest observing the NMR spectrum or image during the course of the reaction. This is not persuasive because this limitation is taught by Rose, as indicated above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


A.L. 7/16/06


LONG V. LE 07/21/06
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600